MDCH Synopsis of Comments for CON Standards Scheduled for 2007 Review
Presented to CON Commission March, 13, 2007

URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY SERVICES/UNITS (Please refer to MDCH staff summary of 1.09.07 comments for additional detail - attached)			
All Identified Issues	Issue Recommended for Review?	Recommended Course of Action to Review Issues	Other/Comments
1. Review mobile requirements; "on-site 23-hour holding unit"	No	None at this time	This has not been demonstrated to be an issue to initiate.
2. Is requirement for parking pad in Section 11(1)(3) still applicable	No	None at this time	This must continue to be in place for facilities that do not perform procedures inside the facility. The standards could be modified to specifically state such.
3. Eliminate language regarding converting fixed units	Possibly	If the Commission chooses to review, draft language can be developed by MDCH staff	Although no fixed machines currently exist in MI, they are still manufactured. Outdated language could be eliminated.
4. Lower expansion volume requirements	No	None at this time	The most recent verifiable data shows that all units perform an average of at least 1800 procedures.
5. Recalculate the factor used to calculate projected procedures	No	MDCH will update this factor and advise the Commission when the change is made	
6. Review replacement and upgrade requirements and make them similar to MRI standards that permits a financial threshold for either move before it requires a CON	No	Review draft language developed by MDCH staff	
7. Develop new language to allow conversion of mobile to fixed units	Possibly	If the Commission chooses to review, draft language can be developed by MDCH staff	It has not been demonstrated that this need exists, although it could be in the future

8. Require that only excess capacity may be committed for initiation of a new service	Yes	Review draft language to correct a "loop-hole" that permits a potential duplicate use of the same procedures	
9. Develop language for "portable" units	Possibly	If the Commission chooses to review, draft language can be developed by MDCH staff	See #7 above
10. Clarify volume criteria in Section (5)(1) to be similar to (5)(4)	Yes	Review draft language based on Section (5)(4) developed by MDCH staff	Volume projections at initiation of services and upon adding of a host site are not clear
11.Delete Comprehensive kidney stone treatment center and all references	Yes	Review draft language developed by MDCH staff that makes deletions	
12-14. Make technical changes and updates that provide uniformity in all CON standards; i.e. Medicaid, consideration of acquisition and relocation, revisions to reference of on-line system	Yes	Review draft language developed by MDCH staff	
Recommendation: The Department suggests that the Commission assign responsibility to department staff to draft necessary technical changes to the standards, along with modified language addressing conversions, for appropriate Commission review and public comment. The department recommends no specific SAC or workgroup activity for these technical changes.			

URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES/UNITS

Summary of 1/9/07 Public Hearing Comments and Department Comments – Working Document

Prepared by: MDCH

Considerations from 1/9/07 Public Hearing.

Public Hearing Summary: The complete oral and written testimonies are included in the March 13, 2007 CON Commission meeting binders. The agencies represented were as follows:

- Spectrum Health (Oral and Written): 1) Review mobile requirements, in particular, the "on-site 23-hour holding unit" requirement for initiation. 2) Does Section 11(1)(e) (parking pad) still apply today? 3) Should Sections 4(3) and 4(6) be eliminated as there are no fixed machines in Michigan? 4) Review expansion volume requirements – should they be lowered? 5) Recalculate the factor for calculating projected UESWL procedures (Appendix A). 6) Review replacement/upgrade, i.e., identify a set dollar amount that could be spent that would not require CON approval similar to MRI standards.

- Greater Michigan Lithotripsy (Oral and Written): Review expansion volume requirements – should they be lowered?

- Economic Alliance of Michigan (Oral and Written): "Although this does not appear to be the trend, there is no language regarding conversion of mobile to fixed units."

- United Medical Systems (Written): 1) Allow only excess capacity to be committed for initiation of a new service. 2) Eliminate the option for converting three fixed units to mobile service as this is no longer needed – no fixed units in the state. 3) Consider language for portable units (mobile units used at a fixed site). 4) Clarify language in Sections 2(1)(l) and 5(1)(b) to reflect Department interpretation. 5) Does not support the elimination of any of the requirements under Section 3(c) as others have suggested. 6) Does not support lowering of the volume requirements for expansion. "The current expansion volume of 1,800 procedures equates to less than seven procedures per day, considering a 250 day annual operation (50 weeks, five days/week). A lithotripsy procedure takes approximately 45 minutes on average, or roughly five and a half hours total for seven procedures per day." 7) Recalculate the factor for calculating projected UESWL procedures (Appendix A). 8) Review replacement/upgrade, i.e., identify a set dollar amount that could be spent that would not require CON approval similar to MRI standards. 9) Draft language provided which also includes the following, in addition to those already mentioned: a) Elimination of Comprehensive kidney stone treatment center and all references as it is no longer needed. b) Modify definition of "initiate a UESWL service." c) For initiation of a mobile UESWL service, an applicant must project at least 100 UESWL procedures in each region in which the proposed mobile UESWL service is proposed to operate. d) Modify language in Section 11(1)(e) to reflect today's practice. e) Modify the methodology for projecting UESWL procedures to be used for expansion of services.

CON Program Section (Discussion with CON Policy Section): 1) Add language under Section 1, Applicability, for Medicaid (technical change being made throughout the CON review standards). 2) Should acquisition and relocation of a unit be considered as has been done in other CON standards vs. acquisition and relocation of a service? 3) Under initiation, Section 3(1)(b), change Section 13 to Section 13(1) – to prohibit the reuse of data. 3) Consider language for portable units (mobile units used at a fixed site). 4) Separate definitions for replace and upgrade instead of the combined definition. 5) Should requirements for conversion from mobile to fixed be added? 6) Other technical changes.

Policy Issues to be Addressed

- Based upon the various testimonies provided, as well as conversations with the CON Program Section and other individuals, the majority of the suggestions are technical in nature and would give further clarity to the current standards. This would not require the use of a Standard Advisory Committee (SAC). The CON Commission could ask the Department to draft language for proposed Action at its June 13, 2007 meeting. A more detailed analysis is included on the following pages.

1. Review mobile requirements, in particular, the "on-site 23-hour holding unit" requirement for initiation. Note: Consideration from 1/9/07 Public Hearing.	
Current Standards	***Policy Perspective***
Sec. 3. (1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following: (a) The capability to provide complicated stone disease treatment on-site. (b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 13. (c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of the following: (i) On-call availability of an anesthesiologist and a surgeon. (ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel. (iii) On-site IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions. (iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator, general radiography and fluoroscopy, cystoscopy, and laboratory services. (v) On-site crash cart. (vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a cardiac intensive care unit. (vii) On-site 23-hour holding unit.	In discussions with CON Program Section, this has not been an issue for obtaining a CON to initiate UESWL services in Michigan. Given that complications can occur and the fact that this has not been a hindrance for obtaining a CON, there should be no change.
2. Does Section 11(1)(e) (parking pad) still apply today? Note: Consideration from 1/9/07 Public Hearing.	
Current Standards	***Policy Perspective***
(e) Each host site must provide a properly prepared parking pad for the mobile UESWL unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.	For those facilities that do not perform the UESWL procedures inside the facility, this requirement needs to remain. However, it may be modified to be only applicable to host sites that do not perform the procedures inside the facility.

3. Should Sections 4(3) and 4(6) be eliminated as there are no fixed machines in Michigan? Note: Consideration from 1/9/07 Public Hearing.	
Current Standards (3) An applicant that demonstrates that it meets the requirements in subdivision (a), (b), or (c) of this subsection shall not be required to demonstrate compliance with Section 4(1): (a)(i) The proposed project involves replacing 1 existing fixed UESWL unit with 1 mobile UESWL unit. (ii) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently. (iii) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 13 are combined for the following, as applicable: (A) All licensed hospital sites committing MIDB data pursuant to Section 14, as applicable, that are located in the region identified in subdivision (iii). (B) All sites that receive UESWL services from an existing UESWL service and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subdivision (iii). (iv) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department. (v) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 13. (b)(i) The proposed project involves replacing 2 or more existing fixed UESWL units with 1 mobile UESWL unit. (ii) The applicant entity is either: a single organization that operates a fixed UESWL service or a joint venture or other arrangement between at least 2 or more organizations that each operates a fixed UESWL service on the date an application is submitted to the Department. (iii) The proposed mobile UESWL service will serve at least 1 host site that is located in a region other than the region or regions in which the fixed UESWL units proposed to be replaced are located currently. (iv) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 13 are combined for the following, as applicable: (A) All licensed hospital sites committing MIDB data pursuant to Section 14, as applicable, that are located in the region identified in subdivision (iv). (B) All sites that receive UESWL services from an existing UESWL unit and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subdivision (iv). (v) A separate application from each host site is filed at the same time the application to replace the fixed units is submitted to the Department. (vi) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 13. (c)(i) The proposed project involves replacing 3 or more existing fixed UESWL units with 1 UESWL unit, either fixed or mobile. (ii) The applicant entity is a joint venture or other arrangement among 3 or more organizations that each operates a fixed UESWL service on the date an application is submitted to the Department. (iii) The combined number of UESWL procedures performed by all of the fixed UESWL units operated by the organizations that are party to the applicant entity is equal to or greater than 1,000 procedures based on the methodology set forth in Section 13. (6) An applicant which can demonstrate that it is a CKSTC with a fixed UESWL unit shall not be required to meet the requirements of Section 4(1) if it can demonstrate the following: (a) The CKSTC has performed at least 2,000 kidney stone treatment procedures during the most recent continuous 12-month period. For the purpose of this subsection, comprehensive kidney stone treatment procedures shall be calculated as the sum of the cystoscopies (ICD-9-CM codes 57.32 and 57.33), nephrostolitohtomies (ICD-9-CM codes 55.03 and 55.04), ureteroscopies (ICD-9-CM codes 56.0, 56.31, and 56.33), and UESWL (ICD-9-CM code 98.51) procedures performed at the CKSTC during the most recent continuous 12-month period. (b) Of the comprehensive kidney stone treatment procedures performed during the most recent continuous 12-month period, at least 600 must have been UESWL procedures. ***Policy Perspective*** Although no fixed machines currently exist in Michigan, they could in the future as stationary units are still manufactured. Subsection (3)(a) should be maintained for converting 1 fixed unit to 1 mobile unit, but subsections (3)(b) and (c) could be eliminated. Subsection (3)(6) is no longer used and can be eliminated.	

4. Review expansion volume requirements – should they be lowered? Note: Consideration from 1/9/07 Public Hearing.	
Current Standards	***Policy Perspective***
(1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In computing this average, the Department will divide the total number of UESWL procedures performed by the applicant's total number of UESWL units, including both operational and approved but not operational fixed and mobile UESWL units.	Sufficient evidence has not been provided - No change recommended.
5. Recalculate the factor for calculating projected UESWL procedures (Appendix A). Note: Consideration from 1/9/07 Public Hearing.	
Current Standards	(vi) The sub-totals from step (v) will then be added to the sub-totals from step (iii) to produce totals for "urban" & "rural" separately per 10,000 population.
(1) Until changed by the Department, the factor to be used in Section 13(1)(b) used for calculating the projected number of UESWL procedures shall be 1.02.	(vii) The percentage difference between "urban" and "rural" discharge rates will be applied to the rate identified in step (a)(iii) above. The result is the revised factor for calculating UESWL procedures.
(2) The Department may amend Appendix A by revising the factor in subsection (1) in accordance with the following steps:	(3) The Department shall notify the Commission when this revision is made and the effective date of the revision.
(a) Steps for determining preliminary statewide UESWL adjustment factor:	***Policy Perspective***
(i) Determine the total statewide number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 for the most recent year for which Michigan Inpatient Database information is available to the Department.	Since it's been at least 3 years since the recalculation, it probably should be updated. This does not require Commission action. The Department is only required to notify the Commission when the factor has been revised and the effective date of the new factor.
(ii) Determine the total number of UESWL procedures performed in the state using the Department's Annual Hospital Questionnaire for the same year as the MIDB being used in subsection (i) above.	
(iii) Divide the number of UESWL procedures determined in subsection (ii) above by the number of inpatient records determined in subsection (i) above.	
(b) Steps for determining urban/rural adjustment factor:	
(i) For each hospital, assign urban/rural status based on the 2000 census. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.	
(ii) The records from step (a)(i) above will then be aggregated by "urban/rural" and zip code.	
(iii) Zip codes that are totally "urban" or "rural" will have the discharges and populations aggregated for those respective groups.	
(iv) For the remaining zip codes with both "urban" and "rural" components, the proportion of the zip code in each part (urban or rural) will be calculated and applied to the population for that zip code.	
(v) These will then be aggregated by discharge and population by urban/rural status.	

6. Review replacement/upgrade, i.e., identify a set dollar amount that could be spent that would not require CON approval similar to MRI standards. Note: Consideration from 1/9/07 Public Hearing.	
Current Standards Section 2(1): (x) "Replace/upgrade a UESWL unit" means a change involving all or part of an existing UESWL unit proposed by an applicant that results in that applicant operating the same number of UESWL units before and after the project completion. Section 4: (4) An applicant that operates a fixed or mobile UESWL unit that is proposing a project involving the replacement/upgrade of an existing UESWL unit, when the capital costs for that replacement/upgrade are $125,000 or less, shall not be required to meet the requirements of subsection (1). This subsection shall apply to the review and decision on only 1 application for the replacement/upgrade of each UESWL unit and on only 1 application at each site.	***Policy Perspective*** After discussion with the CON Program Section, it would seem appropriate to separately define replace and upgrade and not require a CON for upgrades or replacements if below a certain dollar amount.
7. Consider language for conversion of mobile to fixed units. Note: Consideration from 1/9/07 Public Hearing.	
Current Standards Language does not exist.	***Policy Perspective*** This is not an issue at this time. However, it could be an issue in the future, not only for fixed – stationary units, but portable units that stay at a fixed site. Some basic language could be drafted under Section 3 - initiation.
8. Allow only excess capacity to be committed for initiation of a new service. Note: Consideration from 1/9/07 Public Hearing.	
Current Standards Section 3(1): (b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 13. Section 13: Sec. 13. (1) The methodology set forth in this subsection shall be used for projecting the number of UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified in the most recent Michigan Inpatient Database available to the Department on the date an application is deemed complete shall be used for each licensed hospital site for which a signed data commitment form has been provided to the Department in accordance with the provisions of Section 14. In applying inpatient discharge data in the methodology, each inpatient record shall be used only once and the following steps shall be taken in sequence: (a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 shall be counted.	***Policy Perspective*** In discussions with the CON Program Section as well as other individuals, there is a loop hole in the current language. To correct this, it would require a simple change in Section 3(1)(b) – change the reference of Section 13 to Section 13(1). This would mean that for initiation, an applicant could only use MIDB data for reporting projections.

(b) The result of subsection (a) shall be multiplied by the factor specified in Appendix A for each licensed hospital site that is committing its inpatient discharge data to a CON application. If more than one licensed hospital site is committing inpatient discharge data in support of a CON application, the products from the application of the methodology for each licensed hospital site shall be summed. (c) The result of subsection (b) is the total number of projected UESWL procedures for an application that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile service, that does not provide UESWL service, either fixed or mobile, as of the date an application is submitted to the Department.	
9. Consider language for portable units (mobile units used at a fixed site). Note: Consideration from 1/9/07 Public Hearing.	
Current Standards Section 2(1): (l) "Initiate a UESWL service" means to begin operation of a UESWL unit, whether fixed or mobile, at a site that does not offer (or has not offered within the last consecutive 12-month period) approved UESWL services. The term does not include the acquisition or relocation of an existing UESWL service or the renewal of a lease.	***Policy Perspective*** As stated above under item 7, the situation does not exist at this time. However, there could be a time when a facility wants to operate the mobile (portable) unit at a fixed site vs. a mobile route. Basic language to define a fixed portable unit could be drafted if necessary.
10. Clarify language in Section 5(1). Note: Consideration from 1/9/07 Public Hearing.	
Current Standards Section 5: Sec. 5. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following: (a) The proposed mobile UESWL service meets the requirements of Section 3 or 4, as applicable. (b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile UESWL service and its unit(s) shall be included in the CON application submitted by the central service coordinator. (4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL service in a region not currently served by that service shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL service is proposing to add a host site when the results of the methodology in Section 13 are combined for the following, as applicable: (a) All licensed hospital sites committing MIDB data pursuant to Section 14, as applicable, that are located in that region. (b) All sites that receive UESWL services from an existing UESWL service and its unit(s) and propose to receive UESWL services from the proposed mobile service and its unit(s) and that are located in that region. ***Policy Perspective*** If an applicant wants to add a host site to an existing UESWL service in a region not currently served by that service, 100 UESWL procedures must be projected in each region in which the existing mobile UESWL service is proposing to add a host site [Section 5(4)]. In discussions with the CON Program Section and other individuals, it makes sense that this same requirement should be made of those applicants wanting to initiate a new UESWL service. Language similar to Section 5(4) could be drafted for Section 5(1).

11. Elimination of Comprehensive kidney stone treatment center (CKSTC) and all references as it is no longer needed. Note: Consideration from 1/9/07 Public Hearing.	
Current Standards Section 2(1): (f) "Comprehensive kidney stone treatment center" or "CKSTC" means a facility that employs a multi-dimensional approach to the treatment of kidney stones. In addition to a lithotripsy unit, a CKSTC uses holmium lasers, urology endoscopes, ultrasonic, and electrohydraulic stone devices to perform cystoscopies, ureteroscopies, and nephrostolithotomies. A CKSTC has service availability 24 hours a day. Its medical staff is drawn from a multi-county area or is comprised of full-time medical school faculty. A CKSTC has a medical education program that has surgical residents. A CKSTC serves as source of expertise and rarely-used kidney stone devices for other local providers. Section 4: (6) An applicant which can demonstrate that it is a CKSTC with a fixed UESWL unit shall not be required to meet the requirements of Section 4(1) if it can demonstrate the following: (a) The CKSTC has performed at least 2,000 kidney stone treatment procedures during the most recent continuous 12-month period. For the purpose of this subsection, comprehensive kidney stone treatment procedures shall be calculated as the sum of the cystoscopies (ICD-9-CM codes 57.32 and 57.33), nephrostolitohtomies (ICD-9-CM codes 55.03 and 55.04), ureteroscopies (ICD-9-CM codes 56.0, 56.31, and 56.33), and UESWL (ICD-9-CM code 98.51) procedures performed at the CKSTC during the most recent continuous 12-month period. (b) Of the comprehensive kidney stone treatment procedures performed during the most recent continuous 12-month period, at least 600 must have been UESWL procedures.	***Policy Perspective*** After discussions with CON Program Section and other individuals, this is no longer needed and can be eliminated.
12. Add language under Section 1, Applicability, for Medicaid. Note: Consideration from CON Program Section.	
Current Standards Language does not exist.	***Policy Perspective*** Technical change being made throughout the CON review standards.
13. Should acquisition and relocation of a unit be considered as has been done in other CON standards vs. acquisition and relocation of a service? Note: Consideration from CON Program Section.	
Current Standards Language does not exist.	***Policy Perspective*** This is a change that would be consistent with other CON review standards. Language could be drafted based on the other standards.

14. Other technical changes. Note: Consideration from CON Program Section.	
Current Standards	***Policy Perspective***
Sec. 9. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department. Section 10: (2) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent. Section 11: (2) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.	Technical changes being made throughout the CON review standards to accommodate the CON application on-line system.